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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,103	09/11/2000	Eric M. Weaver	P03592US2	4512

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EXAMINER

EWOLDT, GERALD R //

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/659,103	Applicant(s) Weaver et al.
	Examiner G.R. Ewoldt	Art Unit 1644
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
<p>Period for Reply</p> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>		
<p>Status</p> <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Nov 25, 2002</u></p> <p>2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
<p>Disposition of Claims</p> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-24</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>1-8</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>9-24</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
<p>Application Papers</p> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<p>Priority under 35 U.S.C. §§ 119 and 120</p> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>		
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>		
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<p>Attachment(s)</p> <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>9</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>		

DETAILED ACTION

1. Claims 9-24 are being acted upon.
2. Applicant's amendment, remarks, and 132 declaration of Inventor Weaver, filed 11/25/02, are acknowledged.
3. Only the following rejections remain.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 13 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 13 remains indefinite in the recitation of "underweight". As the term is undefined, the metes and bounds of the claim are not defined. The addition to the claim of the phrase "from a starvation period post-weaning" does not serve to define "underweight".
6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
7. Claims 9-18, 21, and newly added Claims 22-24, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,816,252 (IDS) in view of Japan Patent No. 61-132143 (IDS) and U.S. Patent No. 4,623,541 (IDS), for the reasons of record as set forth in Paper No. 6, mailed 5/20/02.

Applicant's arguments, filed 11/25/02, have been fully considered but they are not persuasive. Applicant's traverse the rejection by asserting that the method of adding a globulin concentrate to an animal's water source yielded an unexpectedly improved response when compared to a method of adding a globulin concentrate to an animal's dry feed. A 1.132 declaration of

Inventor Weaver has been submitted in support of this assertion.

Regarding the declaration of Inventor Weaver, said declaration is insufficient to demonstrate the asserted unexpected results. The Declarant indicates that tests were performed that showed an unexpected "daily gain" (it is unclear just what a "daily gain" consists of) and unexpected daily feed intake when a globulin concentrate was added to an animal's water supply. However, the Declarant further indicates that no proper controls were performed as the Declarant merely asserts that "This magnitude of response is well outside the expected response to plasma when included in the dry feed." Accordingly, the results of the test cannot be said to demonstrate anything regarding the addition of a globulin concentrate to dry feed. The Declarant further states that additional trials were conducted with broiler chicks. The Declarant states that the data disclosed in Tables 2 and 3 demonstrate that "the addition of plasma protein to the drinking water resulted in improvements in growth performance well beyond the expected plasma protein response." However, the data of the tables is indecipherable in the instant context. The tables display unexplained + and - signs, as well as unidentified abbreviations, such as D 0-7, ADG. Additionally, all of the numerical results are followed by unidentified superscripts. Accordingly, absent a more complete disclosure, the results of the declaration cannot be considered to support the asserted unexpected results.

Applicant further argues that there is no motivation to combine the references. Applicant then argues that the references individually fail to teach the disclosed invention. It is the Examiner's position that if any of the references taught the invention as a whole, the rejection would have been made under 35 U.S.C. 102(b). The rejection provides motivation for using plasma as a convenient source of the globulin as well as the water supply as a convenient delivery vehicle for the supplement. Accordingly, the rejection is maintained.

8. The following are new grounds of rejection necessitated by Applicant's amendment.

9. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Claims duplicate Claims 9 and 10. Claim 22 differs from Claim 10 only in the changing of "comprises" to "contains", Claim 23 is identical to

Claim 9, and Claim 24 differs from Claim 10 only in the changing of "comprises" to "containing".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9-12 and 14-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of improving weight gain and growth, while decreasing morbidity and mortality in animals during a starvation period post-weaning,

does not reasonably provide enablement for:

a method of improving weight gain and growth, while decreasing morbidity and mortality in animals at times of stress.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The invention of the instant claims is drawn to a method of supplementing an animal's water supply with a globulin concentrate. The specification primarily discloses the administration of the concentrate to pigs during the stressful post-weaning time period. The claims, as now amended, encompass all animals (whether weanable or not), and all stressful situations. At page 12 of the specification a number of additional stressful situations are disclosed. Included in these situations are starvation, surgery, and intentional weight reduction.

While it is conceivable, though extremely unlikely, that an animal might improve weight gain and growth by drinking globulin-supplemented water while starving, it would seem impossible for an animal to improve weight gain and growth by drinking globulin-

supplemented water while in surgery or while undergoing intentional weight reduction. Accordingly, given the breadth of the claims, the instant method must be considered highly unpredictable and unlikely to function as claimed. As such, the claimed method would require undue experimentation to use.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples encompassing the breadth of the claimed invention, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 30, 2003

Patent J. Nolan

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600